31 October 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Comment [Federal Register: September 30, 1999 (Volume 64, Number 189)] [Proposed Rules]

Many tissue banks, while proactive concerning FDA regulations and good manufacturing practices, do not audit their tissue recovery and distribution intermediaries to assure accountability to the same standards that they themselves uphold. These domestic and international intermediaries may have the potential for oversight due to lack of FDA resources.

To maximize leveraged use of resources and to augment domestic and international harmonization, the documentation of audits concerning these issues would help assure FDA's goals of protecting the public health.

Regards.

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